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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lewin, *et al.*

Serial No.: 09/888,358

Filing Date: June 22, 2001

For: CGI-69 COMPOSITIONS AND  
METHODS OF USE)  
) Examiner Quang Nguyen, Ph.D.  
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) Group Art Unit No.: 1636  
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## RESTRICTION RESPONSE

Assistant Commissioner for Patents

Washington, D.C. 20231

Dear Sir:

Responsive to the Official Action of September 27, 2002 Applicants elect, with traverse,  
Group X, Claim 32.

## RESTRICTED GROUPS

The Application has been restricted into 11 groups:

I. Claims 1-9, drawn to an isolated CGI-69 nucleic acid of the presently claimed invention, a vector, and a host cell comprising the same, classified in class 536, subclass 23.5; class 435, subclasses 320.1, 455, for example.

II. Claims 10-12, drawn to an isolated CGI-69 polypeptide of the presently claimed invention, classified in class 530, subclass 350.

III. Claims 13-16, drawn to a CGI-69 fusion protein comprising a polypeptide fused to the carboxy-terminus of a polypeptide comprising an amino acid sequence having at least 80% sequence identity to the sequence of SEQ ID NO:3, classified in class 530, subclass 402.

IV. Claim 17, drawn to an antibody that specifically binds to an isolated CGI-69 of the presently claimed invention, classified in class 424, subclass 130.1.

V. Claims 18-21, drawn to a method of treating a metabolic disorder comprising modulating the activity of CGI-69, wherein said modulating the activity of CGI-69 comprises decreasing the activity of CGI-69.

VI. Claims 18 and 22-24, drawn to a method of treating a metabolic disorder comprising modulating the activity of CGI-69, wherein said modulating the activity of CGI-69 comprises increasing the activity of CGI-69.

VII. Claims 25-28, drawn to a method for determining whether a compound up-regulates or down-regulates expression of a CGI-69 gene in a cell, comprising contacting the cell with said compound and detecting expression of the gene, classified in class 435, subclasses 6, 7.1.

VIII. Claims 29-30, drawn to a transgenic non-human animal having a disrupted CGI-69 gene, classified in class 800, subclass 13.

IX. Claim 31, drawn to a transgenic non-human animal comprising a transgene having at least 80% sequence identity to the sequence of SEQ ID NO:1 or a complement of said sequence, classified in class 800, subclass 13.

X. Claim 32, drawn to a method of screening for a mutation in CGI-69 comprising comparing nucleic acid sequence to the sequence of SEQ ID NOs:1 or 2, classified in class 435, subclass 6.

XI. Claims 33-34, drawn to a method for measuring CGI-69 agonist or antagonist activity of a compound comprising contacting a composition comprising CGI-69 activity with the compound, and determining a change in the CGI-69 activity, classified in class 435, subclass 4.

**Applicants elect, with traverse, Group X, Claim 32.**

## REMARKS

Restriction is only proper if the identified groups are independent or patentably distinct (MPEP §803). The burden is on the Office to provide reasons and/or examples to support its conclusion that the identified groups are independent or distinct.

The Office has characterized the relationship between the products of Groups I, II, III, IV, VIII and IX as unrelated, having chemically unrelated structures that are capable of separate manufacture, use and effect. Even if the chemical structures vary does not mean that they are unrelated. In fact, these products are related. The nucleic acid of Group I encodes the polypeptide of Group II; the fusion protein of Group III will comprise at least portions of the polypeptide of Group II; the antibody of Group IV binds the polypeptide of Group II; the transgenic non-human animal of Group VIII is related to the polynucleotide of Group I (either lacking it because of a targeted knock out, or modified for the same reason), as well as to the polypeptide of Group II (either unstably expressed or not at all); the transgenic non-human animal of Group IX is related to the polynucleotide of Group I and the polypeptide of Group II. Since these products are related, restriction between these groups is improper.

Even though there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, the Office has characterized the methods of Groups V, VI, VII, X and XI as patentably distinct. The Office has stated that methods that are distinct both physically and functionally and are not required one for the other. Applicants note that these Groups are directed to methods, not compositions that would have physical and functional features; Applicants do not understand the Office's argument. The Office has also characterized these methods as having different method steps, starting materials, different desired end-results, and therefore different technical considerations for achieving the end-results. However, the Office has not explained how these asserted characteristics render these groups patentably distinct.

The Office has characterized the product of Group I as related to the methods of Groups V, VI, VII and X as product and processes of use, the same relationship has also been described for Group II to the methods of Groups VI and XI; Group III to Groups VI and XI; and Group IV to Groups V and VII. Citing MPEP § 806.05(h), the Office states that inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product; or (2) the product

as claimed can be used in a materially different process of using that product. The Office's arguments rely on the assertion that the products of Groups I, II, III, IV, VIII and IX are unrelated; however, as noted above, they are in fact related. Thus restriction between these groups is also improper.

The Office has characterized the relationship between the transgenic non-human animal products of Groups VIII and IX as unrelated to the methods of Groups V, VI, VII, X and XI, and therefore they are not required for the practice of any of these methods. The Office has not provided any examples or explanations. The Office has simply stated a conclusion without support.

Applicants submit that the Office has not met the burden necessary in order to sustain the Restriction Requirement. Withdrawal is therefore respectfully requested.

If the Examiner should have any questions concerning this Response, please contact the undersigned.

Respectfully submitted,



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